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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,238	04/16/2004	Alison B. Lukacsko	94902.256172	9635
71398 7590 06/11/2009 STEFAN KIRCHANSKI VENABLE LLP 2049 CENTURY PARK EAST 21ST FLOOR LOS ANGELES, CA 90067				
EXAMINER JAGOE, DONNA A				
ART UNIT		PAPER NUMBER		
1614				
NOTIFICATION DATE		DELIVERY MODE		
06/11/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/826,238

Applicant(s)

LUKACSKO, ALISON B.

Examiner

Donna Jagoe

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 2, 2009 has been entered.

Claims 45-49 are pending in this application.

Applicants' arguments filed April 2, 2009 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 45-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wassenaar U.S. Patent No. 7,060,289 B2 in view of Merck Manual (U).

Wassenaar teaches the method of reducing excessive sweating and minimizing side effects (see abstract) comprising applicant of a topical formulation of glycopyrrolate (an anticholinergic quaternary amine) in a concentration that is from 0.25% to 6% (column 8, lines 29-30). It does not teach the method for killing or inhibiting the growth of microorganisms responsible for fungal infection and non-pathological body malodor. Wassenaar teaches a case study of a patient with excessive sweating of the forehead and groin that resulted in a facial rash and fungal infection. After two weeks of topical application (to the skin surface) the chronic fungal infection of his groin and facial rash had both improved (column 8, lines 32-49).

Merck Manual teaches that athlete's foot, a fungal infection commonly grows in the warm moist areas between the toes.

In holding an invention obvious in view of a combination of references, there must be some suggestion, motivation or teaching in the prior art that would have led a person of ordinary skill in the art to select the references and combine them in the way

that would produce the claimed invention. This motivation may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved. Here, filtered through the nature of the problem to be solved, the prior art disclosed that moist conditions of the skin leads to fungal infection, and that this problem can be addressed by the application of glycopyrrolate solution in a concentration of 0.25-6%. Thus, inhibition of microorganisms and fungus would result in the application of the glycopyrrolate solution, and in the above case study, a fungus infection could be resolved.

Regarding the concentration of the formulation instantly claimed, the amount of glycopyrrolate of Wassenaar et al. is between 0.25% and 6 % which is encompassed by the instantly claimed 0.0001% to about 20 % or from about 0.05% to about 5%. "[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness."

In re Peterson, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003). See also *In re Harris*, 409 F.3d 1339, 74 USPQ2d 1951 (Fed. Cir. 2005).

It would have been made obvious to one of ordinary skill in art at the time it was made to employ the ACQA, glycopyrrolate, to inhibit growth of microorganisms responsible for fungal infection and malodor motivated by the teaching of Wassenaar, who teaches the method of reducing excessive sweating and minimizing side effects (see abstract) comprising applicant of a topical formulation of glycopyrrolate (an anticholinergic quaternary amine) in a concentration that is from 0.25% to 6% (column

8, lines 29-30) and the teaching of Merck Manual that teaches that athlete's foot fungus is a fungal infection that commonly grows in warm moist areas.

Thus the claims fail to patentably distinguish over the state of the art as represented by the cited references.

Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Response to Arguments

Applicant asserts that the experiment reported by Wassenaar possibly demonstrates that reducing the availability of moisture (sweat) can lead to improvement in a facial rash and fungal groin infection, and further extrapolates that epidermal rashes can be ameliorated by a variety of agents including hydrocortisone. The meaning of this assertion is unclear in the context of the application of the prior art to the instant claims. Applicant further asserts that it is unclear from the description in Wassenaar that fungus was at all involved in the rash. In response, Wassenaar clearly states in case study No 1 that the patient had excessive forehead and groin sweating resulting in a facial rash and fungal infection. Topical glycopyrrolate was applied in concentrations of 1% and 1.5% whereby the chronic fungal infection improved. Wassenaar does not recite application of hydrocortisone or any agent other than the glycopyrrolate to the skin surface. Applicant asserts that the experiment does not Wassenaar does not exhibit killing or inhibition of fungi. In response, the improvement of a fungal infection that was previously resistant to treatment is clearly indicative of at least inhibition of the

fungal infection, and although not specifically stated, it would also indicate that the fungi have been killed as well. Further, the claim elements appear in the prior art in the same configuration (the same ACQA - glycopyrrolate), serving the same functions (topically applied in a concentration of from about 0.25% to about 6%), to achieve the same results suggested (inhibit/kill fungi and eliminate non-pathological body malodor).

Applicant asserts that the cited prior art fails to define every element of applicant's invention. As noted in *In re Best* (195 USPQ 430 (CCPA 1977)), and *In re Fitzgerald* (205 USPQ 594 (CCPA 1980)), the mere recitation of newly-discovered function or property, inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same. Applicant asserts that in the instant invention, Applicant was the first to recognize the anti-fungal properties of this class of compounds. In response, Wassenaar teaches the same antifungal properties of glycopyrrolate, the ultimate species selected in the genus of anticholinergic quaternary amines instantly claimed. Applicant states that U.S. Patent Laws clearly allow the patentability of a new use for an old compound and states that "this is clearly the case with the method claimed here". In response, as noted supra, the mere recitation of newly-discovered function or property,

inherently possessed by things in prior art, does not cause claims drawn to those things to distinguish over prior art. In such a situation, the burden is shifted to the applicant to prove that subject matter shown to be in prior art does not possess characteristic relied on where it has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may be inherent characteristic of prior art; whether rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively, burden of proof is same.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe /D. J./
Examiner
Art Unit 1614

June 5, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614